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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/755,085   | 01/08/2004  | Ming H. Wu           | MEM-0005-P            | 8184             |
| 23413  | 7590        | 06/15/2005           | EXAMINER              |                  |
| CANTOR COLBURN, LLP<br>55 GRIFFIN ROAD SOUTH<br>BLOOMFIELD, CT 06002 |             |                      | MORILLO, JANELL COMBS |                  |
|  |             | ART UNIT             | PAPER NUMBER          |                  |
|  |             | 1742                 |                       |                  |

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/755,085             | WU, MING H.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Janelle Combs-Morillo  | 1742                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 January 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-55 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/12/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION*****Claim Objections***

1. Claims 42-46 are objected to because of the following informalities: claims 42-46 are process type claims, dependent on independent product by process claim 41. Because of said dependency, claims 42-46 are interpreted by the examiner to also be product by process type claims. Said claims need to be amended to be consistent with typical product by process preamble claim language. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4-17, 24, 26, 41, 43-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Schetky et al (US 6,258,182).

Schetky teaches examples within the instant  $Mo_{eq}$  range in Table III, alloys 27 ( $Mo_{eq}=10.45$ ), 28 ( $Mo_{eq}=9.22$ ), and 36 ( $Mo_{eq}=9.4$ ). Schetky teaches said alloy has a beta phase (abstract), has linear elastic properties (column 4 line 16), pseudoelastic properties (column 3 line 14), superelastic properties (column 3 lines 27-28), and has a martensitic structure (abstract). Because Schetky teaches examples of a Ti alloy with a  $Mo_{eq}$  amount that falls within the instant range, and wherein said alloy exhibits superelastic and pseudoelastic properties, it is held that Schetky anticipates the presently claimed invention.

Concerning claim 2, the alloy taught by Schetky meets the presently claimed relationship, as determined by the instant the equation for said Mo<sub>eq</sub> in claim 2 (see above reference to examples 27, 28, and 36).

Concerning the process limitations of dependent claims 4, 41, 43-47, Schetky teaches cold working a wire up to 20% reduction, further heat treatment including solution heat treating 780-880°C (column 12 line 60), and aging at 200-400°C (column 11 lines 18) for 0.1-10,000 min (see Fig. 7), which substantially overlaps the presently claimed heat treatment time and temperatures. Said solution heat treatment temperature taught by Schetky overlaps heating above the beta transus.

Concerning claims 5-9, 50, 51, because Schetky teaches a substantially overlapping alloy composition, processed in a substantially similar method, then substantially the same properties, such as elastic recovery are inherently present. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. The *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at

433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), see MPEP 2112.01.

Concerning claims 10, 26, 41, 49, Schetky teaches said alloy has a beta phase (abstract), has linear elastic properties (column 4 line 16), and has pseudoelastic properties (column 3 line 14) and superelastic properties (column 3 lines 27-28), and has a martensitic structure (abstract).

Concerning claims 11-17, 52, 53, which mention said Ti-Mo-Al alloy is in the form of a medical device, Schetky teaches said alloy has excellent biocompatibility and is useful for a variety of medical uses, including: orthodontic arch wires, a stent, catheter, dental implants, bone staples, eyeglass frames (column 3 lines 22-27).

Concerning claims 13, 14, 24, which mention said Ti-Mo-Al alloy is welded, Schetky teaches said alloy exhibits superior weldability (column 2 line 59, column 5 line 15), when said alloy is formed and welded (column 5 line 15).

Concerning claim 47, 48, Schetky teaches said alloy is formed into a wire, for example, 0.4 mm in diameter (column 9 lines 15-16).

Because the prior art teaches examples within the presently claimed alloying ranges, as well as a substantially identical product by process, it is held that Schetky anticipates the presently claimed invention.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 25, 28-30, 34-37, 39, 40, 42, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky et al (US 6,258,182).

Schetky is discussed in paragraphs above. Schetky teaches a beta phase titanium alloy preferably comprising: 10-12% Mo, 2.8-4% Al, 0-2% Cr, and 0-4% Nb (see abstract), which overlaps or touches the boundary of the composition in instant claim 3. While the preferred range taught by Schetky does not overlap the alloys of independent claims 28 and 39, the alloys of claims 28 and 39 fall within the scope of the limits of Mo, Al, Cr, V, and Nb listed in the examples of Schetky in Table III columns 7 and 8, wherein said examples encompass: 8.4-12% Mo, 2.3-3.7% Al, 0-1.8% Cr, 0-1.8% V, 0-3.8% Nb. Overlapping ranges have been held to be a *prima facie* case of obviousness, see MPEP § 2144.05. It would have been obvious to one of ordinary skill in the art to select any portion of the range, including the claimed range, from the broader range disclosed in the prior art, because the prior art finds that said composition in the entire disclosed range has a suitable utility. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Concerning claims 25, 34, 35, which mention said Ti-Mo-Al alloy is welded or brazed, Schetky teaches said alloy exhibits superior weldability (column 2 line 59, column 5 line 15).

Concerning claims 29, 30, 40, as stated in paragraphs above, Schetky teaches said Ti alloy can be made into a variety of medical devices.

Concerning claims 36 and 37, Schetky teaches said alloy has a beta phase (abstract), has linear elastic properties (column 4 line 16), and has pseudoelastic properties (column 3 line 14) and superelastic properties (column 3 lines 27-28), and has a martensitic structure (abstract).

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Concerning claim 42, though Schetky does not teach a product produced by solution heating below the beta transus, the temperature range of solution heating given by Schetky of 780-880°C (column 12 line 60), overlaps the solution heat treatment range given in the instant specification typical of below the transus temperature (see [0056]).

Concerning claims 54, though Schetky does not specify forming said alloy into a file or drill for dental applications, because of the excellent biocompatibility of the Ti-Mo-Al alloy taught by Schetky, it is held to be useful for a variety of medical and dental purposes, such as a file or drill.

6. Claims 18-23, 31-33, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky as applied to claims above, and further in view of Aizawa et al (US 5,658,207).

Schetky does not mention said Ti-Mo-Al alloy is formed into a portion of a golf club. However, Aizawa teaches that titanium alloys can be formed into golf club heads (column 1 line 10), and wherein said golf club head can be secured by welding or press fitting (column 6 lines 54-55). It would have been obvious to one of ordinary skill in the art to form the Ti alloy taught by Schetky into a golf club head taught by Aizawa, because Schetky teaches said alloy has excellent tensile strength properties (column 9 line 20).

7. Claims 27 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky as applied to claims above, and further in view of Davidson (US 6,238,491).

Schetky does not teach the application of a polymer coating to the instant Ti-Mo-Al alloy. However, Davidson teaches that similar Ti alloys used for medical implants can be coated in order to further improve biocompatibility, wherein said coating can be a polymer (column 13 lines 40-46). It would have been obvious to one of ordinary skill in the art to coat the Ti-Mo-Al

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alloy medical device taught by Schetky with a polymer coating as taught by Davidson, because Davidson teaches said coating improves biocompatibility (column 14 lines 40-46).

### ***Double Patenting***

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 28-40 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 26-38 of copending Application No. 10/609004. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 28-40 of the instant application appear to be identical to claims 26-38 of copending Application No. 10/609004.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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11. Claims 1-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/609003. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'003 are also drawn to a composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti; wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'003 at claims 3-10), is produced by solution heating, cold working, cooling in air, aging 350-550°C (US'003 at cl. 2, 11, 12). The Mo<sub>eq</sub> of said alloy taught by the alloy of claims of US'003 meets the Mo<sub>eq</sub> given in instant claims 1, 2, 41, 47.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. 10/755034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'034 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'034 at cl. 4), wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'034 at claims 10-23), is produced an identical process of solution heating, cold working, cooling in air, aging 350-550°C (US'003 at cl. 6, 17, 31). The Mo<sub>eq</sub> of said alloy taught by the alloy of claims 1 and 3 of US'034 meets the Mo<sub>eq</sub> given in instant claims 1, 2, 41, 47.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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13. Claims 1-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-24 of copending Application No. 10/869359. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'359 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'359 at cl. 17), wherein said alloy is held to inherently exhibit an elastic recovery substantially as presently claimed, and said alloy product is produced a process of heat treating and cold working (US'359 at cl. 15, 18). The Mo<sub>eq</sub> of said alloy taught by the alloy of claims of US'359 meets the Mo<sub>eq</sub> given in instant claims 1, 2, 41, 47.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25, 39-53 of copending Application No. 10/609004. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'004 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'004 at cl. 1), wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'004 at claims 3-7), is produced an identical process of solution heating, cold working, cooling in air, aging 350-550°C (US'004 at cl. 40-44). The Mo<sub>eq</sub> of said alloy taught by the alloy of claims of US'004 meets the Mo<sub>eq</sub> given in instant claims 1, 2, 41, 47.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Combs-Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 8:30 am- 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



GEORGE WYSZOMIERSKI  
PRIMARY EXAMINER  
GROUP 1700



JCM  
June 9, 2005